UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

NEUTRINO DEVELOPMENT CORPORATION,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**CIVIL ACTION NO. H-01-2484**
	§	
SONOSITE, INC.,	§	
	§	
Defendant.	§	

MEMORANDUM AND ORDER

Pending before the Court are Neutrino Development Corporation's ("Neutrino") Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Joan Baker (Dkt. #258), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Donald W. Baker (Dkt. #259), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Dr. Don L. Berardinucci (Dkt. #260), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Cameron Weiffenbach (Dkt. #261), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Jens U. Quistgaard (Dkt. #262), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Jens U. Quistgaard on Lack of Infringement by SonoSite's Products (Dkt. #266), Neutrino's Motion to Exclude Testimony of Defendant SonoSite's Expert Witness Lauren S. Pflugrath (Dkt. #267), and Neutrino's Motion to Exclude, or In Limine, the Testimony of Stephen M. Graham (Dkt. #343). The Court, having reviewed the motions, the responses of the parties, and the applicable law, is of the opinion that Plaintiff's motions (Dkt. ## 258, 267, and 343) should be DENIED, Plaintiff's motion (Dkt. # 260) should be GRANTED, and Plaintiff's motions (Dkt. ## 259, 261, 262, and 266) should be GRANTED in part and DENIED in part.

Factual and Procedural Background

This is an action for patent infringement brought by Neutrino Development Corporation ("Neutrino") against Sonosite, Inc. ("Sonosite"). Neutrino is the owner of United States Patent No. 6,221,021 ("the '021 patent"). Neutrino alleges that four devices manufactured and marketed by Sonosite, the Sonosite 180, SonoHeart, Sonosite 180 PLUS, and the SonoHeart PLUS, infringe on the '021 patent.

Richard T. Redano applied for a patent on the device in question on September 9, 1997. (Application Serial No. 08/926, 209). The '021 patent, entitled "Method and Apparatus for Penile Hemodynamic Stimulation, Monitoring, and Drug Delivery Acceleration," resulted from that application. It describes a device for "stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." *U.S. Patent No. 6,221,021* at col. 1, ll. 15-16.

Defendant Sonosite began as a division of ATL Ultrasound, Inc., and was spun off as a public company in April 1998. Sonosite unveiled its first public product in the realm of hand-carried ultrasound devices, the Sonosite 180, on May 17, 1999. Sonosite began selling the device in June 1999. In January 2000, Sonosite launched its second product, the SonoHeart. In April 2001, Sonosite launched a new generation of these two devices with its introduction of the SonoSite 180 PLUS and the SonoHeart PLUS.

On July 24, 2001, Neutrino filed this action, alleging that Sonosite had illegally used Redano's invention and infringed the '021 patent. Sonosite answered the complaint on August 14, 2001, asserting that the '021 patent claims are not infringed and are invalid, and counterclaimed for declaratory judgment of non-infringement and invalidity.

On February 20, 2002, after extensive briefing, the Court held a one-day *Markman* hearing

on claim construction. On October 9, 2002, the Court stayed all proceedings pending the Court's *Markman* and summary judgment rulings. The Court issued its claim construction on August 21, 2003. Subsequently, the Court granted Neutrino's Motion for Summary Judgment on Infringement (Dkt. #136) finding that Sonosite's devices literally infringed the '021 patent and the reverse doctrine of equivalents was not applicable (Dkt. #162). Consequently, Sonosite's case for trial focuses on the invalidity of the '021 patent, which requires expert testimony about the '021 patent and certain prior art. Neutrino has objected to the testimony of the above-named seven Sonosite experts.

Expert Testimony Standard

Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

This "imposes a special obligation upon a trial judge to 'ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Kuhmo Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999) *(*quoting *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). The expert testimony must be relevant, not simply in the sense that all testimony must be relevant under Federal Rule of Evidence 402, but also in the sense that the expert's proposed opinion is based on a valid scientific inquiry. *Daubert*, 509 U.S. at 592.

The Supreme Court has provided five non-exclusive factors to consider when assessing whether the methodology upon which an expert rests his opinion is scientifically reliable. These factors are (1) whether the expert's theory can be or has been tested, (2) whether the theory has been

subject to peer review and publication, (3) the known or potential rate of error of a technique or theory when applied, (4) the existence and maintenance of standards and controls, and (5) the degree to which the technique or theory has been generally accepted in the scientific community. *Daubert*, 509 U.S. at 593–94; *Burleson v. Texas Dept. of Criminal Justice*, 393 F.3d 577 (5th Cir. 2004). The test for determining reliability is flexible and can adapt to the particular circumstances underlying the testimony at issue. *Kumho Tire*, 526 U.S. at 150–51. The party seeking to have the district court admit expert testimony must demonstrate by a preponderance of the evidence that the expert's findings and conclusions are reliable, but need not show that the expert's findings and conclusions are correct. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998).

Discussion

I. Joan Baker

Ms. Baker's testimony pertains to whether certain amendments made to the '021 patent specification constituted a "new matter" and were therefore improperly included under the patent.[1] For such an amendment to be properly included it must be inherently supported in the original patent application. 35 U.S.C. § 132. That is, a person of ordinary skill in the art could have looked at the patent application as of the filing date and determined that the claimed invention included the later-claimed subject matter. *Turbocare Div. of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-19 (Fed. Cir. 2001). Neutrino objects to Ms. Baker's testimony on three grounds: (1) Ms. Baker is not qualified to give expert opinions on the "ordinary level of skill in the art" for the '021 patent; (2) Ms. Baker has failed to determine what "one of ordinary skill in the art" would recognize from the initial disclosures of the '021 patent; and (3) Ms. Baker's opinions are

[1] *See* Sonosite's Exhibit 12. Amendments made via letter of May 4, 2000 and letter of November 14, 2000.

conclusory and are not supported by any of the reliability factors recognized under *Daubert*.[2]

Sonosite opposes Neutrino's contention that Ms. Baker's qualifications are wanting on the grounds that she is a "pioneer" in the field of medical ultrasound and has extensive experience with the use and operation of diagnostic medical ultrasound devices.[3] The Court acknowledges that Ms. Baker's resume and professional experience support Sonosite's characterization of her qualifications. However, Ms. Baker's qualifications must allow her to offer opinions from the perspective of "one of ordinary skill in the art." The appropriate level of ordinary skill in the art is a complex factual inquiry within an abstract legal standard. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991). Although the finder of fact will ultimately decide the level of ordinary skill in the art, the Court must determine the relevant art area as a matter of law in order to determine whether particular experts are qualified under *Daubert*. Courts have long acknowledged the difficulty of this task. Judge Learned Hand, writing for the Second Circuit Court of Appeals before the regional appellate courts were rescued from such matters in 1982, quipped that, "[w]hen all is said, we are called upon imaginatively to project this act of discovery against an hypostatized average practitioner, acquainted with all that has been published and all that has been publicly sold. If there be an issue more troublesome, or more apt for litigation than this, we are not aware of it." *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950).

The "new matter" defense at bar requires the hypothetical person of ordinary skill in the art to be able to construe the '021 patent application and thereby understand what comprises the claimed invention. The specific issue at bar is whether the hand-held nature of the ultrasonography generator

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[2] Dkt. #258, p. 2.

[3] Dkt. #300, at 1-4.

claimed in the amendment was inherent in the original patent application. The Court finds that the relevant art area for making this determination is the "designing, testing and building" of medical ultrasound devices.[4] The law does not require an expert opining from the perspective of "one of ordinary skill in the art" to have the same qualifications as the inventor or even be an inventor herself. *See Orthopedic Equip. Co. v. All Orthopedic Appliances*, 707 F.2d 1376, 1382 (Fed.Cir.1983). But it does require that she is sufficiently qualified to construe the patent and understand the design and components of the claimed invention as one with ordinary skill in the art of designing, testing, and building medical ultrasound devices.

Ms. Baker's report and curriculum vitae establish that her qualifications are in the relevant art area. Ms. Baker's experience consulting on the design features of prototype medical ultrasound devices and considering the ergonomic aspects of medical ultrasound devices qualify her to opine about what design features would be inherently understood from the description of the ultrasonography generator in the original patent application.[5] The ability of a user to hold a component of the device in his hand is specifically an ergonomic issue. Whether such an ergonomic feature is inherently described in the original patent application is something about which Ms. Baker is qualified to testify under *Daubert*.

Neutrino also challenges Ms. Baker's testimony on the grounds that she has not properly resolved the skill level of one of "ordinary skill in the art." Neutrino argues that, because Ms. Baker has failed to determine the level of ordinary skill in the art, her opinions are irrelevant because they are not offered from the legally requisite perspective. "In determining [the level of ordinary skill

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[4] Sonosite's Exhibit 10. This formulation of the relevant art area clarifies the Court's broader formulation in Dkt. #325, p.6.

[5] Sonosite's Exhibit 12, pp. 1-3.

in the art], the [trier of fact] may consider various factors including 'type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.'" *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (*quoting Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962-63 (Fed. Cir. 1986)). Neutrino objects to Ms. Baker's failure to establish the level of skill she applied to her analysis through the investigation of these factors. In order for Ms. Baker's testimony to be relevant to the issue of "new matter," Sonosite must establish that she has knowledge of the level of ordinary skill in the art and that she has applied that perspective to her testimony. Any disagreement between the parties about what constitutes the level of ordinary skill would present a fact issue to be resolved by the jury. However, Neutrino claims that Ms. Baker has failed to offer *any* factual basis that could be evaluated by the jury.[6] The Court disagrees. In her deposition, Ms. Baker testified that she considered the level of ordinary skill in the art to be a person who "has been trained and passed one's credentialing examinations . . ."[7] This statement is sufficient to allow the jury to determine whether this is the appropriate level of ordinary skill in art. Neutrino's disagreement with Ms. Baker's formulation of the level of ordinary skill goes to the weight of her testimony, not to its admissibility.

Finally, Neutrino objects to the reliability of Ms. Baker's testimony on the grounds that (1) she failed to consider all the patents incorporated by reference in the '021 patent, (2) she did not understand the terms "ultrasound generator" and "ultrasonography generator," (3) she only considered one embodiment of the Pohl patent, and (4) she incorrectly concludes that it would

[6] Dkt. #258, pp. 4-6.

[7] Sonosite's Exhibit 15, at 59.

require 4 hands to operate the device described in the '021 patent. Neutrino's allegation that Ms. Baker failed to consider all of the patents incorporated by reference in the '021 patent is based on her admission that she did not use United States Patent No. 5,565,466 disclosed to Gioco et al. ("the '466 patent") in preparing her report.[8] Neutrino argues that this admitted omission renders her evaluation of the '021 patent incomplete and therefore unreliable under *Daubert*. Materials incorporated by reference in a patent are effectively part of the patent as though they were explicitly included in their entirety within the patent document. *Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). Ambiguous terms within the patent can sometimes be interpreted in light of disclosures made in the materials incorporated by reference. The "new matter" issue relevant to Ms. Baker's testimony focuses on the ambiguity of the term "ultrasonography generator" in the '021 patent. Proper evaluation of that term would require Ms. Baker to interpret it in light of disclosures made in the patents incorporated by reference in the '021 patent. Ms. Baker explains in her deposition testimony that she did not consider the '466 patent and did not include it with her report because its disclosures were irrelevant to opinions about the size of the ultrasonography generator in the '021 patent. The '466 patent discloses a method for enhancing sexual stimulation by introducing a vasodilator agent into circulation to improve blood flow to the genital region. The '466 patent does not involve or discuss medical ultrasound devices or disclose any information that could have informed Ms. Baker's conclusions about the size of the ultrasonography generator described in the '021 patent. Therefore, the Court finds that Ms. Baker's exclusion of the '466 patent from her report was appropriate under the circumstances and does not compromise the reliability of her testimony.

[8] Dkt. #258, at 15.

Neutrino also argues that Ms. Baker admitted in her deposition testimony that she did not understand the terms "ultrasound generator" and "ultrasonography generator" and therefore her testimony about the meaning of these terms is uninformed and unreliable.[9] Ms. Baker explained in her report that the "terms 'Ultrasonography Generator' and 'Ultrasound Generator' are not terms typically used in the field of ultrasound, and have no special meaning."[10] Similarly, Ms. Baker's subsequent deposition testimony that she could not be sure what Mr. Redano meant by those terms in the '021 patent simply indicated that those terms did not have meaning in common usage independent of the '021 patent. Nothing in Ms. Baker's report or deposition testimony indicates that her understanding of the those terms was deficient. Ms. Baker's specific understanding of the meaning of those terms is a matter ripe for cross-examination.

Neutrino also challenges Ms. Baker's testimony on the grounds that her report only considered one embodiment of United States Patent No. 5,578,060 disclosed to Pohl et al. ("Pohl patent"). Neutrino has taken the position that the original '901 patent application inherently disclosed a portable, hand-held ultrasonography generator by incorporating by reference the Pohl patent. Ms. Baker concluded in her report that the Pohl patent did not describe a hand-held device.[11] Neutrino challenges the reliability of Ms. Baker's conclusion on the grounds that she failed to evaluate the entirety of the Pohl patent. Sonosite argues that Neutrino's challenge goes to the weight of Ms. Baker's testimony, not to its admissibility. The Court agrees. The reliability inquiry under *Daubert* asks the Court to consider the methodology the expert employed to reach her conclusion,

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[9] *Id.* at 16.

[10] Sonosite's Exhibit 12, p. 4.

[11] *Id.* at 8-10.

not the accuracy of the conclusion itself. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998). Ms. Baker's report discusses several aspects of the Pohl patent and specifically considers Mr. Redano's claims about the Pohl patent. Neutrino presents no evidence that Ms. Baker's evaluation of the Pohl patent was deficient for purposes of determining whether or not that patent disclosed a hand-held component equivalent to the ultrasonography generator in the '901 and '021 patent applications. Sonosite suggests, and the Court agrees, that the accuracy of Ms. Baker's conclusions about the Pohl patent are a matter ripe for cross-examination and not appropriate grounds for exclusion.

Finally, Neutrino challenges the reliability of Ms. Baker's testimony on the grounds that her report improperly concludes that four hands would be required to operate the device disclosed in the '021 patent. Neutrino objects to Ms. Baker's reliance on "the originally filed application from which the '021 Patent claims priority."[12] Neutrino contends that the appropriate focus should have been the "invention," which it defines as "the claims of the patent."[13] However, the Federal Circuit has explained that "[t]he written description requirement and its corollary, the new matter prohibition of 35 U.S.C. § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date." *Turbocare*, 264 F.3d at 1118. New claims and any other added material must find support in the *original* specification. Therefore, the Court finds that Ms. Baker properly focused her "new matter" analysis on the specification in the original patent application.

As for Neutrino's disagreement with Ms. Baker over the numbers of hands required to hold

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[12] Dkt. #258, at 20.

[13] *Id.* at 21.

different components and turn different knobs, the Court finds that such a factual controversy is more appropriate for cross-examination. Therefore, the Court finds that Ms. Baker's testimony is admissible under *Daubert*.

II. Donald W. Baker

Mr. Baker's testimony pertains to whether the '021 patent would have enabled a person of ordinary skill in the art at the time the patent application was filed to make and use the claimed invention without undue experimentation. 35 U.S.C. § 112; *Adang v. Frischhoff*, 286 F.3d 1346, 1355 (Fed. Cir. 2002); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Neutrino objects to Mr. Baker's testimony on five grounds: (1) Mr. Baker's underlying expertise was out-dated at the time the '021 patent was filed; (2) Mr. Baker has demonstrated no knowledge of the level of ordinary skill in the art; (3) Mr. Baker's "real world feasibility" testimony is irrelevant and unreliable; (4) Mr. Baker failed to exclusively focus on the claims of the '021 patent; and (5) Mr. Baker failed to properly consider the patents incorporated by reference in the '021 patent.

Neutrino challenges Mr. Baker's qualifications to testify from the perspective of one of ordinary skill in the art at the time the patent application was filed on the grounds that he had been retired from the field for 12 years at the time of the filing in 1997. Mr. Baker's curriculum vitae confirms that he held his last professional position in the field in 1983. Furthermore, during his deposition, Mr. Baker conceded that "many advances" in medical ultrasound technology and in the miniaturization of electronic components used in commercial products had taken place in the 12-year period between his last professional position in the field and the date the '021 patent was filed.[14] Sonosite contends that Mr. Baker remained current in the field through teaching, consulting, and

[14] Dkt. #259, Exhibit B, p.71.

reading professional journals and was thereby knowledgeable about the level of ordinary skill in the art in 1997. Sonosite further argues that Mr. Baker's retirement from the field is not sufficient to disqualify him as an expert. The Court agrees that the simple fact that Mr. Baker was retired in 1997 does not, in and of itself ,disqualify his testimony; however, the relevant inquiry under the enablement defense requires Mr. Baker's knowledge to be contemporary to the patent application filing. Mr. Baker testifies in his supplemental declaration that he kept abreast of developments in the field through consulting, teaching and various other activities from the time of his retirement through the time of the filing date of the '021 patent application.[15] Mr. Baker also explicitly qualifies his explanation of the level of skill in the art in terms of his knowledge of the field in 1997. Thus, the Court finds that Mr. Baker's knowledge of the field was not out-dated in 1997. Any objections that Neutrino maintains about Mr. Baker's specific consideration of issues relevant to the field in 1997 are appropriate material for cross-examination.

Neutrino also objects generally to the sufficiency of Mr. Baker's knowledge of the level of ordinary skill in the art in 1997. Neutrino's assertion that Mr. Baker "has no idea how to *legally* determine the level [of ordinary skill in the art]. . ." (emphasis added) misapprehends the proper inquiry into the level of ordinary skill in the art. The relevant analysis is factual. *Ryko Mfg.*, 950 F.2d at 718. Mr. Baker's factual conclusions about the level of ordinary skill in the art are under the purview of the jury so long as the Court determines that his testimony is reliable. Neutrino contends that the absence of analysis underlying Mr. Baker's factual conclusions about the level of ordinary skill fails the reliability analysis set forth under *Daubert*. However, Mr. Baker's conclusions about the level of ordinary skill in the art are nonscientific expert opinions based on specialized

[15] Sonosite's Exhibit 31.

knowledge. *See* MCCORMICK ON EVIDENCE § 13. Where scientific knowledge is not at issue, the Court need not use the *Daubert* factors to determine reliability, but may gauge reliability from a more flexible analysis. *Kumho Tire*, 526 U.S. at 149. Mr. Baker's opinions as to the level of ordinary skill in the art are necessarily based on his own experience. In his supplemental declaration, Mr. Baker sets forth the education and experience necessary to be one of ordinary skill in the art and explains that he derived these standards from his own experience working and teaching in the field.[16] The Court is satisfied that Mr. Baker has ample experience in the field to reliably opine about the level of ordinary skill in the art.

Neutrino also argues that Mr. Baker's "real-world feasibility" testimony is not relevant because it "is not a correct focus in an enablement analysis."[17] The Federal Circuit Court of Appeals has articulated the test for enablement as follows:

> A decision on the issue of enablement requires determination of whether a person skilled in the pertinent art, using the knowledge available to such a person and the disclosure in the patent document, could make and use the invention without undue experimentation.

Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 941 (Fed. Cir. 1990). Neutrino contends that testimony by Mr. Baker about the "feasibility" of designing the patented invention subjects the patent to a more rigorous analysis than that demanded by the "make and use . . . without undue experimentation" requirement of § 112. Specifically, Neutrino offers portions of Mr. Baker's deposition testimony that suggest Mr. Baker equated "feasibility" with commercial success.[18] The Federal Circuit has made clear that the requirements of § 112 do not require evidence that the

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[16] *Id.*

[17] Dkt. #258, p.13.

[18] *Id.* at 14.

patented device could be manufactured commercially. *See Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1562 (Fed. Cir. 1987). Sonosite contends that Mr. Baker's opinions are relevant because they (1) "are expressed from the appropriate point of view (ordinary skill in the art)," and (2) "address the appropriate inquiry (undue experimentation)." Sonosite suggests that Mr. Baker's use of the term "feasibility" was essentially short hand for the factors the Federal Circuit has stated a court may consider in determining whether a disclosure would require undue experimentation.[19] It appears from Mr. Baker's report that he used the terms "feasibility" and "enablement" more or less interchangeably. In his deposition testimony, Mr. Baker concedes that he used the term "feasibility" to mean the ability of one of ordinary skill in the art to make and use a "commercially acceptable product." In fact, Mr. Baker responded affirmatively to a deposition question about whether the prototype he considered would be "a final package ready for commercialization. . . ." "Title 35 does not require that a patent disclosure enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003). Because Mr. Baker's analysis is based on a standard inapplicable to the proper inquiry under § 112, his testimony cannot assist the jury to resolve any fact relevant to Sonosite's enablement defense. The research and development model set forth in Mr. Baker's report simply answers the wrong

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[19] Factors:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999) (quoting *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

question and, as such, is inadmissible under Federal Rule of Civil Procedure 402.

Thus, the Court finds that Mr. Baker may properly testify as to the ordinary level of skill in the art at the time of the '021 patent filing, but cannot testify as to enablement under § 112 based on the analysis contained in his report.

III. Don L. Berardinucci

Neutrino objects to the testimony of Dr. Berardinucci on the grounds that it is both irrelevant and unreliable. Neutrino's relevancy objection focuses on the contentions that Dr. Berardinucci's qualifications as a urologist are not relevant to his testimony about the utility of the patented device and his analysis focuses exclusively on one method contained in the '021 patent description that need not be practicable for the '021 patent to be useful under 35 U.S.C. § 101.

Sonosite argues in response to Neutrino's relevancy objections that Dr. Berardinucci's testimony is not offered to establish a utility defense under § 101, but to suggest a lack of enablement under § 112. It appears that the confusion stems from Dr. Berardinucci's use of the term "operability" instead of "utility" or "enablement." However, Neutrino also contends that Dr. Berardinucci's opinions about whether "the device described and claimed in the '021 patent 'would cure erectile dysfunction by applying ultrasound energy to the penis in order to stimulate blood flow'"[20] are not relevant to *any* issue at bar. To support this contention, Neutrino advances a theory of patent construction that appears in various Neutrino pleadings dealing with the enablement defense. Essentially, Neutrino argues that the claims of the '021 patent do not describe a therapeutic device intended to stimulate blood flow in the penis in order to accelerate drug delivery to that region. Neutrino points out in other pleadings and deposition questioning that the claims of the '021

[20] Dkt. # 260, p.2 (citing Berardinucci Report, Exhibit A, p.1).

patent do not mention a penis or anything at all about erectile dysfunction, stimulating blood flow, or drug delivery.

The Court agrees that the claims of the '021 patent only expressly describe a device used to monitor various hemodynamic parameters. If § 112 only requires the '021 patent description to enable one of ordinary skill in the art to make and use this diagnostic device, then obviously testimony about whether the claimed device could achieve the therapeutic goals set forth in the description is irrelevant. The first paragraph of 35 U.S.C. § 112 states:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The enablement requirement of § 112 demands that the patent specification enable "those skilled in the art to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed.Cir.1993)). The question the Court must resolve is what portions of the '021 patent compose the "claimed invention." Neutrino's enablement arguments rely on the "claimed invention" consisting of only the patent claims. Conversely, Sonosite's expert testimony on the issue of enablement indicates that Sonosite considers the therapeutic method outlined in the Summary of the Invention to be part of the "claimed invention."[21]

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[21] Obviously, Section 112 expressly describes the "claimed invention" in terms of the written description in the specification. *See Markman v. Westview Instruments, Inc.*, 32 F.3d 967, 979 (Fed. Cir. 1995). The Court does not interpret Neutrino's argument to mean that the specification should be ignored all together, but that the parts of the specification that do not specifically interpret the terms of the claims are without the scope of the "claimed invention." For example, under Neutrino's interpretation, that portion of the specification describing the components of the diagnostic device would be within the scope of the "claimed invention," whereas any reference to a penis in the specification would not be within the scope of the

Because "the scope of the claims must be less than or equal to the scope of the enablement," *Nat'l Recovery Tech., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999), it follows that the scope of the enablement may be broader than the claims. However, the written description need not enable anything broader than the scope of the claims. The fact that the claims dictate the minimum scope of enablement does not make all portions of the written description that do not literally and exactly reflect the terms of the claims irrelevant. To the contrary, enablement is determined based on the written description, and the features giving purpose to a claimed device in the written description are relevant to enablement even if absent in the literal terms of the claims. *See Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999). For purposes of determining whether the enablement requirement of § 112 has been satisfied, the Court considers the claims interpreted in light of the specifications and drawings and the underlying purpose of the invention. The claims demarcate an area of invention within the exclusive possession of the patentee. The requirement that the patent description be enabling is the quid pro quo the patentee must offer in exchange for exclusive possession. The written description in the patent must allow others in the field to realize this new technology and put it to use. Therefore, the claimed invention cannot be interpreted in the absence of the underlying purpose of the patent. *See Decca, Ltd. v. United States*, 210 Ct.Cl. 546, 544 F.2d 1070, 1077 (Ct. Cl. 1976) ("The machine patented may be imperfect in its operation; but if it *embodies the general principle* and works . . . it is enough.") (emphasis added).

The 27 claims of the '021 patent only describe "an apparatus . . . to monitor hemodynamic

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"claimed invention" because a penis is not mentioned in the claims. Conversely, Sonosite seems to embrace a process of interpretation that would include the entire written description in the specification.

parameters." However, the written description instructs that the "invention is directed toward a method and apparatus for stimulating and/or monitoring hemodynamic activity, such as blood flow, in a penis." The claims must be interpreted in light of this broader assertion. Because the described invention is for "stimulating *and/or* monitoring" (emphasis added), the claimed invention can monitor without the ability to stimulate.[22] Because the claims do not discuss stimulation, and because the specifications do not require the ability to both monitor *and* stimulate, the Court finds that the "claimed invention" is "directed toward a method and apparatus for monitoring hemodynamic activity. . . ." However, because the general principle underlying the invention was expressly the treatment of erectile dysfunction, the Court finds that the "claimed invention," for purposes of the enablement analysis, is directed specifically and exclusively at the penis. Therefore, the Court finds that, in order for the '021 patent to satisfy the requirements of § 112, the patent description must enable one of ordinary skill in the art to make and use an apparatus capable of measuring hemodynamic activity in a penis.

The Court will analyze the relevance of Dr. Berardinucci's testimony in light of this interpretation of the "claimed invention" under the enablement defense. Neutrino contends that the analysis in Dr. Berardinucci's report is based entirely on the incorrect assumption that the '021 patent claims a therapeutic device. The Court agrees. Dr. Berardinucci states in his report that "I have been asked to review [the '021 patent], and form a professional, medical opinion as to whether the device described and claimed in that patent would cure erectile dysfunction by applying

[22] The Court considered at length the possibility that the "and/or"designation might describe a device capable of both stimulating and monitoring, but with the ability to only do one or the other at a time. Although the descriptions support this interpretation, the explicit reference only to a monitoring capability in the claims leads the Court to conclude that only this use is part of the claimed invention.

ultrasound energy to the penis in order to stimulate blood flow."[23] Because that analysis is not relevant to Sonosite's enablement defense, Dr. Berardinucci's opinions are irrelevant.[24]

IV. Cameron Weiffenbach

Neutrino objects to the testimony of Cameron Weiffenbach on the issues of "new matter" and "inequitable conduct" on the grounds that both are irrelevant and unreliable. Specifically, Neutrino objects to the relevancy of Mr. Weiffenbach's critique of the Patent Office practices and procedures and his testimony about Richard Redano's status as a registered patent attorney. Neutrino also argues that Mr. Weiffenbach's testimony about "new matter" and "inequitable conduct" are not supported by any of the *Daubert* reliability factors. Finally, Neutrino contends that certain portions of Mr. Weiffenbach's testimony are impermissible instructions on the law to the jury.

Neutrino concedes that Mr. Weiffenbach's general testimony regarding the patenting process and Patent Office ("PTO") procedures are appropriate expert testimony that he is qualified to offer. However, Neutrino objects to testimony suggesting deficiencies in the PTO process that might serve to undermine the presumption of validity afforded final determinations of the PTO.[25] Sonosite argues that Mr. Weiffenbach's testimony that the patent examiner committed several errors during prosecution of the '021 patent is relevant to the issue of whether or not Richard Redano deliberately

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[23] Dkt. # 260, Exhibit A, p.1.

[24] The Court notes that, even if the claimed invention did include the therapeutic method contained in the description, Dr. Berardinucci's testimony would be irrelevant because he states that he does not express any opinion about whether or not ultrasound energy transmitted into the penis would stimulate blood flow. Dr. Berardinucci's testimony is only that ultrasound energy could not cause an erection. The '021 patent never suggests that ultrasound energy could cause an erection. The therapeutic method in the description suggests that ultrasound energy could stimulate blood flow in the penis and thereby accelerate the delivery of drugs designed to cure erectile dysfunction.

[25] The presumption of validity is codified at 35 U.S.C. § 282.

took advantage of an error by the PTO to include a "new matter" in the '021 patent. Sonosite contends that Mr. Weiffenbach's testimony establishes that the PTO made errors and that Redano would have recognized those errors and therefore the amendment made to the '021 patent was procured through inequitable conduct. Neutrino argues, however, that evidence of problems in the PTO prosecution is not admissible. To support this contention, Neutrino cites to a case where a district court refused to allow an expert "to speculate about possible defects, errors, or omissions in the application process." that would serve to undermine the presumption of validity afforded final determinations by the PTO. *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 255-56 (W.D.N.Y. 2000).

The Court finds that, to the extent that Mr. Weiffenbach's testimony simply addresses the potential pressures and potential for error at the PTO, such testimony is inadmissible. *See American Hoist & Derrick Co. v. Sowa, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984). Such general testimony tends to undermine the presumption of validity. However, the fact that invalidity defenses are permitted indicates that the presumption of validity is a rebuttable presumption. Evidence of mistakes or misconduct during the patent prosecution are relevant to determining the actual validity (as opposed to the presumed validity) of the patent. "[T]he examiner's and the applicant's absolute compliance with the internal rules of the patent examination" is relevant where there is evidence of inequitable conduct. *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960-61 (Fed. Cir. 1997). Therefore, the Court finds that testimony about specific PTO errors in the prosecution of the '021 patent are admissible to show inequitable conduct.

For similar reasons, the Court finds that testimony that Richard Redano was a registered patent attorney at the time of the patent prosecution is proper. Sonosite contends that "registered

patent attorneys are presumed to know the patent law and PTO rules and procedures."[26] The Court agrees that the jury could reasonably find that Richard Redano's trained knowledge of patent law suggests that he would have been aware of certain PTO errors and consequently, that he took advantage of those errors and expanded the scope of the '021 patent through fraud.

Neutrino also objects to Mr. Weiffenbach's opinion that Richard Redano's legal conclusion that "no new matter has been added" in the May 4th amendment and the November 14th amendment was a misrepresentation to the PTO on the grounds that "Mr. Redano's legal arguments to the Patent Office cannot, as a matter of law, constitute inequitable conduct."[27] Neutrino contends that "statements of fact or legal arguments made by the prosecuting party" are immaterial to the issue of a patent's validity.[28] Sonosite argues that this is not true in the context of an inequitable conduct defense. The Court agrees. Neutrino's characterization of the presumption of validity suggests that the law presumes that the patent examiner did not rely on misrepresentations made by the applicant. To the contrary, if the misrepresentations made were material, the law presumes that the entire application was tainted by deceit. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995); *see also* 37 C.F.R. § 1.56 (2003). Therefore, material representations made by Richard Redano to the PTO during the prosecution are relevant to the issue of inequitable conduct. That clarified, the Court finds, however, that Mr. Weiffenbach's opinions about the misrepresentative nature of Mr. Redano's statements to the PTO are based on opinions he is unqualified to offer. As set forth in the following paragraphs the Court finds that Mr. Weiffenbach is unqualified to testify about whether

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[26] Dkt. #301, p. 28.

[27] Dkt. #261, p. 20.

[28] *Id.* at 21.

the amendments made to the '021 patent were in fact "new matter."

Neutrino contends that Mr. Weiffenbach is not qualified to testify about whether or not material contained in the May 4th and November 14th amendments was "new matter" on the grounds that he is not "one of ordinary skill in the art." Neutrino claims that the relevant inquiry is whether one of ordinary skill in the art would have understood that the material contained in the amendments was "new matter." The Court has already resolved the art area as "the designing, testing, and building" of medical ultrasound devices. Sonosite does not argue that Mr. Weiffenbach is skilled in this area, but instead contends that he is particularly qualified to consider the patent application materials from the perspective of a patent examiner and patent attorney and his testimony serves to tie the technical opinions of Dr. Jens Quistgaard and Ms. Joan Baker on the issue of "new matter" to the prosecution record of the '021 patent. For an amendment to a patent application to comply with 35 U.S.C. § 132, *a person of ordinary skill in the art* must be able to look at the patent application as of the filing date and determine that the claimed invention included the later-claimed subject matter. *Turbocare Div. of Demag Delaval Turbomach. Corp. v. Gen. Elec. Co.*, 264 F.3d 1111, 1118-19 (Fed. Cir. 2001). The law makes no exception for the expert testimony of patent examiners, patent attorneys, or any other patent law experts. If the witness is unqualified to testify from the perspective of "one of ordinary skill in the art," then his testimony is inadmissible on the issue of "new matter." Therefore, the Court agrees with Neutrino that Mr. Weiffenbach is not qualified to testify as to whether the amendments constituted "new matter" as prohibited by the written description requirement of § 112.

The Court's finding that Mr. Weiffenbach is not qualified to testify as to whether amendments made to the '021 patent constituted "new matter" seriously limits the scope of his testimony about errors made during the patent prosecution. Mr. Weiffenbach can properly testify

as to any actual defects that occurred in the application process, but he is not qualified to identify any amendment made to the '021 patent as "new matter" and, therefore, cannot properly conclude that the patent examiner committed an error by failing to identify such as "new matter." Mr. Weiffenbach's testimony should be strictly limited to a general examination of the patent application process and any specific irregularities in prosecution of the '021 patent that he is qualified to identify. *See Bausch & Lomb, Inc. v. Alcon Laboratories, Inc.*, 79 F. Supp. 2d 252, 255-56 (W.D.N.Y. 2000) (only allowing expert witness who was a former patent examiner to testify about general patent application process and any "evidence that there actually were defects in the particular application process at issue."); *see also Applied Materials, Inc. v. Advanced Semiconductors Materials America, Inc.*, 1995 WL 261407, *3 (N.D.Cal. Apr. 25, 1995). Similarly, Mr. Weiffenbach's testimony about misrepresentations made by Richard Redano should be limited to defects in the particular application process that a patent attorney would have recognized, and should not convey any opinion about whether or not Redano would have recognized the amendments made to the '021 patent as "new matter." However, other opinions about Redano's knowledge, such as knowledge that "he was supposed to particularly point out support in the original filed '021 Patent application for his statement that 'no new matter has been added'"[29] are appropriate.

Neutrino also objects to certain portions of Mr. Weiffenbach's testimony as improper instructions on the law to the jury. Specifically, Neutrino contends that Mr. Weiffenbach's opinion that Redano did not conceive of the claimed device and Mr. Weiffenbach's opinion regarding the explicit or inherent disclosures of the '901 patent are impermissible instructions to the finder of fact. Certainly, Neutrino is correct to point out that witness testimony regarding what the law requires

[29] Dkt. #310, p.37.

is unnecessary and improper. *See Owen v. Kerr-McGee Corp.*, 698 F.2d 236, 239-40 (5th Cir. 1983). Sonosite argues that Mr. Weiffenbach's testimony is not designed to instruct the jury on the law because it is "couched in terms of the evidence that the expert considered."[30] However, the Court finds that portions of Sections B and C on pages 60 and 61 of Mr. Weiffenbach's report attempt to explain the legal standards as opposed to offering appropriate conclusions in terms of legal standards. Therefore, that portion of Mr. Weiffenbach's testimony regarding the concept of priority that explains how a claim is entitled to a particular filing date is an unnecessary explanation of the law that should be excluded. Furthermore, Mr. Weiffenbach is not qualified to testify about the claimed device under the '901 patent. As discussed above, Mr. Weiffenbach is not one of ordinary skill in the art and therefore his testimony about facts necessary to establish the understanding of one of ordinary skill in the art is not helpful to the trier of fact.

Similarly, that portion of Mr. Weiffenbach's testimony regarding inventorship that explains the legal standard for inventorship and conception is not an appropriate subject for expert testimony. Furthermore, the Court finds that the subsequent testimony regarding the disclosures made in the '021 patent are inadmissible as Mr. Weiffenbach is unqualified to opine about what one of ordinary skill in the art would understand from the written description and claims of the '021 patent. Contrary to Sonosite's assertion, "specialized knowledge and experience in the patent field" does not automatically qualify Mr. Weiffenbach to testify about every aspect of the '021 patent.

Finally, Neutrino objects to Mr. Weiffenbach's testimony regarding the disclosure of the Pohl Patent (U.S. Patent No. 5,578,060) on the grounds that he is not qualified to testify as one of ordinary skill in the art. Contrary to Sonosite's argument that "Mr. Weiffenbach's 30 years of

[30] Dkt. #301, p. 43 (citing *Fiataruolo v. United States*, 8 F.3d 930, 942 (2d Cir. 1993)).

experience as a patent practitioner and former patent examiner qualify him to offer this testimony," the law demands that testimony on the disclosures of a patent be offered from the perspective of one of ordinary skill in the art. *See Adang v. Frischhoff*, 286 F.3d 1346, 1355 (Fed. Cir. 2002); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Mr. Weiffenbach's experience in the field of patent lawyering is simply irrelevant and his testimony about the Pohl Patent is inadmissible.

V. Jens U. Quistgaard

Neutrino seeks to exclude the testimony of Jens Quistgaard ("Dr. Quistgaard") in two motions. The first motion claims that there is no reliable basis for Dr. Quistgaard's opinions on "new matter," "enablement," and "anticipation," and further that opinions regarding examiner error are impermissible. The second motion contends that Dr. Quistgaard's "lack of infringement" opinions are unreliable and should be excluded.

First, Neutrino asserts that Dr. Quistgaard's "new matter" testimony is unreliable because it is not offered from the perspective of one of ordinary skill in the art. Neutrino contends that Dr. Quistgaard "has not established that he possesses any specific knowledge of who 'one of ordinary skill in the art' is, or what this individual would have concluded from reading the patent application at the time of its filing."[31] Sonosite argues that Dr. Quistgaard did qualify the conclusions of his report in terms of "one of ordinary skill in the art" and that Neutrino failed to question him about what he believes the level of ordinary skill in the art to be and whether he applied that standard to his opinions. The Court believes that the following introductory passage from Dr. Quistgaard's report resolves the issue of the application of the "one of ordinary skill in the art" standard:

> As a result of my education and experience, I am very familiar with medical ultrasound technology, and designing, testing and building medical ultrasound

[31] Dkt. #262, p. 3.

> devices, including analyzing their structure and how they function and perform. I believe that I am an expert in this field and can provide opinions on how one with ordinary skill in this art would understand the structure, function and performance of devices described in patent disclosures such as ones in U.S. patents 5,947,901 and 6,221,021.[32]

The Court is satisfied that Dr. Quistgaard's qualifications support this opinion. Any exception Neutrino takes to Dr. Quistgaard's formulation or application of the level of ordinary skill in the art is a factual dispute ripe for cross-examination.

Neutrino also objects to Dr. Quistgaard's "enablement" opinions on the grounds that he failed to conduct analysis from the perspective of one of ordinary skill in the art and he failed to focus on the invention claimed in the '021 patent. As discussed above, the Court is satisfied that Dr. Quistgaard has conducted his analysis from a legally acceptable formulation of the level of ordinary skill in the art. If Neutrino disagrees with the facts underlying Dr. Quistgaard's formulation and application of that standard, it is free to explore the basis for its disagreement on cross-examination. Neutrino's contention that Dr. Quistgaard failed to focus on the "claimed invention" when analyzing the '021 patent under § 112 is based on the same excessively narrow interpretation of the "claimed invention" discussed above in relation to the testimony of Dr. Berardinucci. Neutrino objects to Dr. Quistgaard's reliance on the proportions of the device depicted in the drawings on the grounds that the Court's claim construction simply described the ultrasonography generator as "[a] body that is sized such that it can be held by hand and, so held, moved from one location to another." However, as the Court discussed above, construction of the claims to determine the scope of possession for purposes of identifying infringement is different than analysis of the claimed invention for purposes of determining enablement under § 112. The enablement analysis asks whether the written

[32] Dkt. # 262, Exhibit A, Quistgaard Report, p. 24.

description, including the drawings, allows enablement at least as broad as the scope of the claims. If Neutrino contends that the written description in the '021 patent would enable one of ordinary skill in the art to make and use a device with capabilities at least as broad as the claims, it is appropriate for Sonosite's enablement expert to look to the written description, including the drawings to see if they so instruct. Neutrino's objection to this testimony is misplaced.

Neutrino also objects to Dr. Quistgaard's opinions regarding patent examiner error on the ground that such testimony is an inappropriate attempt to rebut the presumption of validity afforded a duly granted patent. Sonosite argues in response that Dr. Quistgaard's opinion is not generalized testimony about problems in the PTO, but identifies specific defects in the prosecution of the '021 patent that undermine its validity. As discussed above, the presumption of validity is a rebuttable presumption and therefore does not preclude all evidence of patent prosecution defects. The prohibition against generalized testimony about problems in the PTO articulated in cases such as *Bausch & Lomb, Inc. v. Alcon Labs., Inc.*, 79 F. Supp. 2d 252, 255-56 (W.D.N.Y. 2000), and *Applied Materials, Inc. v. Adv. Semiconductor Materials America, Inc.*, 1995 WL 261407, *3 (N.D. Cal. 1995), is designed to prevent the burden of proof from being shifted to the party defending a patent's validity upon a showing of irregularities in the patent prosecution. Even evidence of specific prosecution defects, such as that offered in Dr. Quistgaard's testimony, cannot shift the burden of proof from the defendant. However, this does not make specific evidence of prosecution defects irrelevant. As the Court explained above, evidence of specific prosecution defects can be relevant to the issue of inequitable conduct. Dr. Quistgaard offers his opinion that two erroneous statements were made by the patent examiner in connection with his investigation into "new matter." Dr. Quistgaard's testimony is essentially that Richard Redano made incorrect statements about the hand-held nature of the ultrasonography generator to the patent examiner and that the patent

examiner erroneously found support for the hand-held amendment in a patent incorporated by reference in the original patent application.[33] Testimony about the patent examiner's allegedly erroneous interpretation of United States Patent No. 5,983,783 is relevant to the issue of "new matter" and, therefore, admissible.

Finally, Neutrino contends that there is no reliable basis for Dr. Quistgaard's opinion that the Diasonics ultrasound device anticipates the claims of the '021 patent on the grounds that Dr. Quistgaard offers no facts to support this conclusion in his report. Typically, testimony concerning anticipation must identify each claim element, state the witnesses' interpretation of the claim element and explain in detail how each claim element is disclosed in the prior art reference. *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002). Testimony is insufficient if it is merely conclusory. *Id.* Dr. Quistgaard states in his deposition testimony that he based his conclusion on a comparison of the claims of the two devices, but fails to explain how each claim of the '021 patent is disclosed in the claims of the Diasonics patent. As such, Dr. Quistgaard's testimony on the issue of anticipation of the Diasonics device is not sufficiently reliable under *Daubert* and is therefore inadmissible.

In its second motion pertaining to the testimony of Dr. Quistgaard, Neutrino contends that his opinions on "lack of infringement" are unreliable on the grounds that (1) the Court has already determined that Sonosite's "old products" literally infringe the '021 patent, (2) Dr. Quistgaard's reverse doctrine of equivalents analysis is flawed as a matter of law, (3) Dr. Quistgaard failed to apply the Court's *Markman* claim construction, and (4) Quistgaard incorrectly applies an invalidity defense to his infringement analysis.

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[33] Dkt. #262, Exhibit A, pp. 3-4.

Neutrino contends that Dr. Quistgaard's opinion that "none of Sonosite's medical ultrasound products infringe any of the claims"[34] of the '021 patent is inappropriate because the Court already found that certain Sonosite products literally infringe the '021 patent.[35] Sonosite argues in response that the Court's rulings did not apply to 5 of the 9 Sonosite products that Neutrino alleges infringe the '021 patent. Both Parties are correct. Dr. Quistgaard's testimony that the Sonosite 180, the Sonosite 180 PLUS, the SonoHeart, and the SonoHeart PLUS do not literally infringe the '021 patent or are so far changed from the claimed invention in the '021 patent as to not infringe under the reverse doctrine of equivalents is irrelevant because the Court has already held otherwise. That is, the Court has already determined that these products do literally infringe the '021 patent and the reverse doctrine of equivalents does not apply. However, the Court's previous Order does not address the SonoHeart Elite, the iLook 15, the iLook 25, the TITAN, and the MicroMaxx. As the Court has not resolved the issue of infringement with regard to these five newer devices, Dr. Quistgaard's testimony on the matter is still relevant. However, to the extent that any of Dr. Quistgaard's testimony relies on an interpretation of the '021 patent claims and written description that does not include an ultrasonography generator contained within a body sized to be hand-held, such testimony is irrelevant. The Court has held, and has reemphasized several times, that the claims of the patent include an ultrasonography generator within a "body that is sized such that it can be held by hand . . . ." The Court has found that the claims of the patent include such a description of the ultrasonography generator for purposes of determining literal infringement and that the written description includes the ultrasonography generator within a hand-held body for

[34] Dkt. #266, p.2.

[35] Dkt. #162.

purposes of determining enablement under § 112 and for evaluating infringement under the reverse doctrine of equivalents.[36]

Sonosite contends that the written description and the claims were improperly amended to include the "sized to be hand-held" language and that, therefore, the patent should not be read to include a hand-held ultrasonography generator for purposes of determining infringement and applying the reverse doctrine of equivalents. Sonosite's argument confuses the distinct analyses applied to a determination of infringement and a determination of invalidity. If Richard Redano amended the '021 patent to include matter that was not supported in the original patent application, then that "new matter" invalidates the entire patent. If the patent is invalid, obviously Sonosite's devices cannot infringe it. However, the Court's infringement analysis is applied presuming the validity of the patent. The Court did not evaluate whether the amendments made to the '021 patent in May and November of 2000 were "new matter" when determining that the Sonosite devices then at bar literally infringed the '021 patent. Nor did the Court evaluate the amendments for "new matter" when deciding that Sonosite had failed to produce evidence that the reverse doctrine of equivalents should apply. Dr. Quistgaard is certainly qualified to testify about "new matter," as the Court found above, but, to the extent that Dr. Quistgaard's opinions about infringement assume that "new matter" was improperly added to the '021 patent, those opinions are irrelevant. If the Court or the jury finds that "new matter" was improperly added to the '021 patent, then the Court's finding

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[36] U.S. Pat. No. 6,221,021, preferred embodiment:

> . . .the display is located or mounted in a portable unit, such as the ultrasonography generator. As shown in Fig. 2, the ultrasonography generator unit is sized to be grasped or held in a user's hand. In the preferred embodiment shown in Fig. 3, the system is physically housed or located within the ultrasonography generator unit.

of literal infringement is irrelevant because the '021 patent is invalid. But, the finding of infringement and the application of the reverse doctrine of equivalents is based strictly on the formulation of the '021 patent the PTO accepted and is presented to this Court as U.S. Pat. No. 6,221,021. With that limitation articulated, the Court declines to determine at this time whether or not the finding of literal infringement as to the Sonosite 180, the Sonosite 180 PLUS, the SonoHeart, and the SonoHeart PLUS applies to the SonoHeart Elite, the iLook 15, the iLook 25, the TITAN, and the MicroMaxx.

VI. Lauren S. Pflugrath

Neutrino challenges the reliability of Lauren S. Pflugrath's "anticipation" and "obviousness" opinions on the grounds that he failed to consider and properly apply the perspective of "one of ordinary skill in the art." Neutrino also objects to Mr. Pflugrath's "obviousness" opinions on the grounds that he failed to consider any of the *Graham* factors in his analysis.

Neutrino contends that Mr. Pflugrath failed to make any investigation into the appropriate level of ordinary skill in the art and that, consequently, his opinions on "anticipation" and "obviousness" are unreliable. Neutrino contends that the absence of factual analysis underlying Mr. Pflugrath's conclusions applying the level of ordinary skill fails the reliability analysis set forth under *Daubert*. However, Mr. Pflugrath's conclusions about the level of ordinary skill in the art are nonscientific expert opinions based on specialized knowledge. *See* MCCORMICK ON EVIDENCE § 13. Where scientific knowledge is not at issue, the Court need not use the *Daubert* factors to determine reliability, but may gauge reliability from a more flexible analysis. *See Kumho Tire*, 526 U.S. at 149. Mr. Pflugrath's opinions as to the level of ordinary skill in the art are necessarily based on his own experience. Mr. Pflugrath qualified his opinions on "obviousness" and "anticipation" by stating that the '021 patent's defects would be evident to one of ordinary skill in the art.

Furthermore, when questioned about the level of skill applied, Mr. Pflugrath began to explain the knowledge that one of ordinary skill in the art would possess, but was interrupted by Neutrino's counsel.[37] Mr. Pflugrath explained in his errata sheet to that deposition that he developed his understanding of the level of ordinary skill in the art from his experience designing, testing, and building medical ultrasound devices. The Court is satisfied that Mr. Pflugrath understood and employed the "one of ordinary skill in the art" standard to his opinions on "anticipation" and "obviousness." The appropriate level of ordinary skill in the art of designing, testing, and building medical ultrasound devices is a factual determination to be resolved by the jury. Neutrino correctly points out that, if Mr. Pflugrath testified based on his own perspective and that he possesses "extraordinary," not ordinary, skill in the art, then his conclusions are improper. *See Custom Accessories v. Jeffrey-Allan*, 807 F.2d 955, 962 (Fed. Cir. 1986); *Environmental Designs, Ltd. v. Union Oil Co. of California*, 713 F.2d 693 (Fed. Cir. 1983) (holding that "one of ordinary skill in the art" is not a judge, layman, those skilled in remote arts, or "the geniuses in the art."). However, Mr. Pflugrath never asserts that he applied his own perspective to his "anticipation" and "obviousness" analysis. Expert witnesses quite often have *extraordinary* skill in the art and are perfectly capable of evaluating the level of *ordinary* skill and applying that perspective. The witness himself need not be the hypothetical ordinary artisan. The hypothetical person of ordinary skill in the art is a legal construct. Neutrino is free to challenge Mr. Pflugrath's formulation of the level of ordinary skill in the art on cross-examination.

Neutrino also contends that Mr. Pflugrath's "obviousness" opinions are unreliable because he failed to analyze any of the secondary considerations (i.e. *Graham* factors) that he articulated in

[37] Dkt. #267, Exhibit C, pp. 79-80.

his Report. "Under section 103, a patent may not be obtained if the differences between the claimed invention and the prior art are such that the invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the invention pertains." 1 PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 1.30 (2d ed.). Four facts must be determined to establish the "obviousness" of a patented device. First, what is shown or disclosed by the pertinent prior art must be determined. Second, the differences between the claimed invention and the prior art must be identified. Third, there must be an assessment as to the level of ordinary skill in the art to which the invention related at the time the invention was made. Finally, the circumstances that surround the historical origins of the claimed invention and its effect on the industry must be considered. *See Graham v. John Deere Co.*, 383 U.S. 1 (1966). Neutrino argues that Mr. Pflugrath's "obviousness" opinions are unreliable because he failed to consider the fourth step of this factual analysis. Specifically, Neutrino contends that Mr. Pflugrath failed to consider the commercial success of the infringing Sonosite devices. The Supreme Court has held that evidence of commercial success may be a relevant indication of nonobviousness. *Graham*, 383 U.S. at 17-18. Sonosite argues in response that "Mr. Pflugrath explicitly recognized in his report that 'when making a determination of obviousness various factors must be considered so as to avoid the use of hindsight, such as whether the invention . . . was commercially successful . . . .'"[38] The Court agrees that Mr. Pflugrath's statement indicates that he was aware of the relevance of the *Graham* factors to the obviousness analysis. Mr. Pflugrath's opinions are not unreliable simply because he did not concede Neutrino's contention that the commercial success of Sonosite's devices indicates that the claimed invention in the '021 patent was nonobvious. Mr. Pflugrath's testimony presents

[38] Dkt. #291, p.6 (quoting Dkt. #267, Exhibit A, pp. 3-4).

facts relevant to the obviousness analysis. Factual evidence that tends to contradict Mr. Pflugrath's conclusions is appropriate material for cross-examination.

VII. Stephen M. Graham

Neutrino objects to the testimony of Stephen Graham on the grounds that Sonosite failed to timely designate him as an expert witness. Sonosite contends that Mr. Graham will only testify as a fact witness about legal actions with which he was involved as Sonosite's corporate counsel. Neutrino concedes that Mr. Graham was disclosed as a fact witness, but contends that his testimony on the legal effect of certain Securities and Exchange Commission ("SEC") filings cannot qualify as "lay testimony" under Federal Rule of Evidence 701. Sonosite argues that "Mr. Graham's testimony concerning [SEC filings] will consist exclusively of recounting, as a matter of historical fact, what Sonosite did, and why."[39] The Court agrees that this is proper testimony from a fact witness. Neutrino has had sufficient notice of Mr. Graham's role as corporate counsel to Sonosite and his specific involvement with the SEC filings at issue. Therefore, the Court finds that Mr. Graham may properly testify as a fact witness about matters with which he was personally involved, including advice he gave, as Sonosite's corporate counsel.

CONCLUSION

For the foregoing reasons, the Court finds that Plaintiff's motions to exclude (Dkt. #s 258, 267, and 343) should be DENIED, Plaintiff's motion to exclude (Dkt. # 260) should be GRANTED, and Plaintiff's motions to exclude (Dkt. #s 259, 261, 262, and 266) should be GRANTED in part and DENIED in part.

It is so ORDERED.

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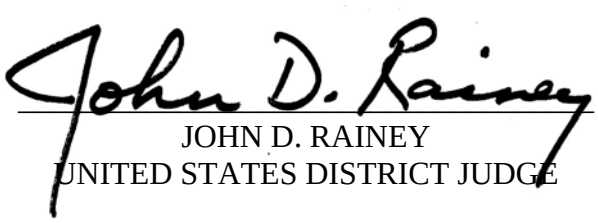
[39] Dkt. #349, p. 5.

Signed this 23rd day of January, 2006.



JOHN D. RAINEY
UNITED STATES DISTRICT JUDGE